forthcoming public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on April 6, 2021, from 9 a.m. Eastern Time to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions including information regarding special accommodations due to a disability may be accessed at: *https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings.*

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, *aden.asefa@fda.hhs.gov,* 301–796–0400, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On April 6, 2021, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application for the TransMedics Organ Care System (OCS) Heart, by TransMedics, Inc. The proposed Indication for Use for the TransMedics OCS Heart, is as follows: The TransMedics Organ Care System (OCS) Heart System is a portable extracorporeal heart perfusion and monitoring system indicated for the resuscitation, preservation, and assessment of donor hearts in a near-physiologic, normothermic, and beating state intended for a potential transplant recipient.

OCS Heart is indicated for donor hearts with one or more of the following characteristics:

- Expected cross-clamp or ischemic time ≥4 hours due to donor or recipient characteristics (*e.g.,* donor- recipient geographical distance, expected recipient surgical time); or
- Expected total cross-clamp time of ≥2 hours PLUS one of the following risk factors:
  - Donor Age ≥55 years; or
  - Donors with history of cardiac arrest and downtime ≥20 minutes; or
  - Donor history of alcoholism; or
  - Donor history of diabetes; or
  - Donor Left Ventricular Ejection Fraction ≤50 percent but ≥40 percent; or
  - Donor history of Left Ventricular Hypertrophy (septal or posterior wall thickness of >12 and ≤16 mm); or
  - Donor angiogram with luminal irregularities but no significant coronary artery disease.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/advisory-committees/circulatory-system-devices-panel/2021-meeting-materials-circulatory-system-devices-panel.* Select the link for the 2021 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 30, 2021. Oral presentations from the public will be scheduled on April 6, 2021, between approximately 1 p.m. Eastern Time and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 22, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 23, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallet at *Artair.Mallet@fda.hhs.gov* or 301–796–9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 25, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–04371 Filed 3–2–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1411]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for Data To Support Cross-Center Collaboration for Social Behavioral Sciences Associated With Disease Prevention, Treatment, and the Safety, Efficacy, and Usage of Food and Drug Administration Regulated Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a proposed collection

of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by April 2, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is ''Generic Clearance for Data to Support Cross-Center Collaboration for Social Behavioral Sciences Associated with Disease Prevention, Treatment, and the Safety, Efficacy, and Usage of FDA Regulated Products.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for Data To Support Cross-Center Collaboration for Social Behavioral Sciences Associated With Disease Prevention, Treatment, and the Safety, Efficacy, and Usage of FDA Regulated Products

OMB Control Number 0910–NEW

FDA is seeking to conduct qualitative and quantitative research studies to better understand consumers', patients', caregivers', academic/scientific experts', and public health professionals' perceptions and behaviors regarding various issues and outcomes associated with disease prevention, treatment, and the safety and efficacy of all FDA-regulated products. These studies may consist of small groups, focus groups/town halls, individual indepth interviews, and surveys relating to the evaluation of disease prevention and treatment and the safety, efficacy, and usage of FDA-regulated products; the studies may also include communication messages and strategies, and other materials directed to consumers, patients, caregivers, and public health professionals (*e.g.,* evaluate the effectiveness of communication messages, educational materials, and interventions directed toward promoting and protecting human and animal health).

Among the general provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is charged with promoting the public health through regulatory oversight as well as clinical research. Specifically, section 1003(d)(2)(C) and (D) of the FD&C Act (21 U.S.C. 393(d)(2)(C) and (D)) provides that the Commissioner of Food and Drugs shall be responsible for research. Accordingly, FDA is seeking to conduct qualitative and quantitative research studies.

The information collection is intended to support research conducted by, or on behalf of, FDA. Understanding consumers', patients', caregivers', academic/scientific experts', and public health professionals' perceptions and behaviors plays an important role in improving FDA's decision-making processes and communications impacting various stakeholders. To better understand consumers', patients', caregivers', academic/scientific experts', and public health professionals' perceptions and behaviors regarding various issues and outcomes associated with disease prevention, treatment, and the safety, efficacy, and usage of products overseen by the Agency, FDA is requesting approval of this generic information collection request.

The qualitative and quantitative research anticipated by FDA aligns with Agency objectives. For example, among eight scientific priorities is the goal to support social and behavioral sciences. Such research helps the Agency meet this goal by:

- Identifying gaps in the target audiences' knowledge regarding FDA-regulated products, and outcomes associated the disease prevention and treatment;
- reaching diverse audiences;
- assessing target audiences' knowledge, perceptions, and behaviors about FDA-regulated products;
- evaluating the effectiveness of FDA's communications;
- exploring ways to incorporate patient input into decision making;
- leveraging real-world data;
- evaluating outcomes; and
- integrating the knowledge gained from the research into Agency communications, activities, interventions, and programs.

FDA will only submit a collection for approval under this generic clearance if it meets the following condition: Information provided by respondents will be kept private and anonymous, except as otherwise required by law. This will be communicated to respondents by means of introductory letters, explanatory texts on the cover pages of questionnaires, scripts read prior to focus groups or telephone interviews, and consent forms as appropriate. Respondents also will be advised of the following: (1) The nature of the activity; (2) the intended purpose and use of the data collected; (3) FDA sponsorship (when appropriate); and (4) the fact that participation is voluntary at all times. Because responses are voluntary, respondents will be assured that there will be no penalties if they decide not to respond, either to the information collection as a whole or to any individual questions.

Only Agency or Agency-sponsored personnel will have access to individual-level surveys, interviews, or focus group data. All project staff from a contractor or cooperative agreement grantee conducting the information collection must take required measures to ensure respondent privacy and confidentiality of data. Personally identifiable information (PII) shall be limited to data that may be required in the process of respondent enrollment. PII will be accessible to only those contractors or cooperative agreement grantees who need it and will not be linked to interview data. Neither FDA employees nor any Federal employee of any other Agency will have access to PII. All PII will be destroyed by contractors as soon as feasible following data collected during interviews.

All electronic and hard-copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers; hard-copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy and anonymity, all data will be reported to FDA in aggregate form, with no links to individuals preserved. Reports generated by this information collection will be used only for research purposes and for the development of communication messages.

Social and behavioral testing efforts described in this proposal are typically considered exempt from the ''Regulations for the Protection of Human Subjects'' in accordance with 45 CFR 46.101(b)(3). Before data are collected, FDA researchers must obtain either an exemption or an expedited or full approval for all research from FDA's institutional review board (IRB).

When FDA's IRB determines that minors are capable of giving assent, the

IRB shall determine whether adequate provisions are made for soliciting assent. Generally, assent requires securing the signature of a minor potentially participating in the research on a separate assent form, in addition to the consent form the parent or legal guardian signs. An assent document should: (1) Contain an explanation of the study; (2) a description of what is required of the subject (*e.g.,* what he or she will experience (whether the minor will be in the hospital, whether the minor's parents will be with him or her, etc.)); (3) an explanation of any risks and pain associated with the study; (4) an explanation of any anticipated change in the minor's appearance; and (5) an explanation of the benefits to the minor or others.

FDA plans to use the data collected under the generic clearance to inform the following information for education, interventions, outcomes, regulatory science programs, materials and resources, and disease prevention and treatment. FDA expects the data to guide the formulation of the Agency's educational and public health objectives on FDA-regulated products and support development of subsequent research efforts. The data will not be used to make policy or regulatory decisions. Rather, these data will: (1) Inform FDA's public education campaigns and other educational/interventional materials directed to informing consumers, patients, caregivers, and public health professionals about human and animal health issues; and (2) provide information on the safety, efficacy, and usage of FDA-regulated products.

If these conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process.

To obtain approval for a collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB, along with supporting documentation (*e.g.,* a copy of the interview or moderator guide, screening questionnaire).

FDA will submit individual qualitative and quantitative collections under this generic clearance to the OMB. Individual collections will also undergo review by FDA's IRB, senior leadership for the primary investigator's respective offices, and PRA specialists.

Description of Respondents: The respondents to this collection of information are all FDA stakeholders, including general population individuals, as well as consumers of certain products, patients and their caregivers, academic/scientific experts, individuals from specific target labor groups, such as physicians, medical specialists, pharmacists, dentists, nurses, veterinarians, dietitians, and other public health professionals.

In the **Federal Register** of July 7, 2020 (85 FR 40655), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although five comments were received, they were not responsive to the four collection of information topics solicited and, therefore, will not be discussed in this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews/Surveys/Focus Groups	2,520	14.6	36,792	0.25 (15 minutes)	9,198

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This is a new collection of information whose total estimated annual reporting burden is 9,198 hours. The number of participants to be included in each individual generic submission under this collection of information will vary, depending on the nature of the compliance efforts and the target audience.

Dated: February 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–04407 Filed 3–2–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIAMS.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIAMS.

Date: April 27–28, 2021.

Time: April 27, 2021, 12:30 p.m. to 4:45 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 10 Center Drive, Bethesda, MD 20892, (Virtual Meeting).

Time: April 28, 2021, 12:00 p.m. to 4:15 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 10 Center Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: John J. O'Shea, MD, Ph.D., Scientific Director, National Institute of Arthritis & Musculoskeletal and Skin Diseases, Building 10, Room 6N204, Bethesda, MD 20892, (301) 496–2612, *osheajo@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: _February 25, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–04366 Filed 3–2–21; 8:45 am]

BILLING CODE 4140–01–P